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From: Nassif, Julianne (DPH)
Sent: Tuesday, August 04, 2009 9:38 AM
To: Caloggero, Dina (DPH); DiNatale, Margaret (DPH); Jenner, Jennifer (DPH)
Cc: Han, Linda (DPH)
Subject: RE: PT survey - OPNA

ok w/ me too.

From: Caloggero, Dina (DPH)
Sent: Tuesday, August 04, 2009 9:30 AM
To: DiNatale, Margaret (DPH); Nassif, Julianne (DPH); Jenner, Jennifer (DPH)
Cc: Han, Linda (DPH)
Subject: RE: PT survey - OPNA

2:30 is fine with me...

From: DiNatale, Margaret (DPH)
Sent: Tuesday, August 04, 2009 9:25 AM
To: Nassif, Julianne (DPH); Jenner, Jennifer (DPH); Caloggero, Dina (DPH)
Cc: Han, Linda (DPH)
Subject: RE: PT survey - OPNA

Hi,
I can't meet at 1 pm. I am facilitating a QA conference call on Biomonitoring.

I can meet after 2:30 pm; this will give me time to clean up after the call and to eat lunch.

Let me know if that time works.

Thanks,
Peggy

From: Nassif, Julianne (DPH)
Sent: Monday, August 03, 2009 3:49 PM
To: DiNatale, Margaret (DPH); Jenner, Jennifer (DPH); Caloggero, Dina (DPH)
Cc: Han, Linda (DPH)
Subject: RE: PT survey - OPNA

Peggy, Dina, Jennifer,
I am happy to meet about this. How's Tuesday 1:00 PM?
Julie

From: DiNatale, Margaret (DPH)
Sent: Monday, August 03, 2009 3:38 PM
To: Nassif, Julianne (DPH); Jenner, Jennifer (DPH)
Cc: Caloggero, Dina (DPH); Han, Linda (DPH); DiNatale, Margaret (DPH)
Subject: PT survey - OPNA

Hi Julie and Jennifer,

I think this matter may be better addressed in a meeting. At this time, I don't feel comfortable passing this documentation onto Dr. Han. I don't think this will take much effort to get everything in order and we can probably get it done, if we all sit down to discuss it. I don't want to appear to be holding this up, I want to make sure that all of the documentation is appropriate and can stand on its own in two years, if it is audited during the next inspection.

Today I received the OPNA PT survey back. I also received the corrective action for this PT survey, along with some attachments that document email communications between Julie and Bob K. and a set of what look like presentation slides, without a title and a page signed by the analysts.

Needless to say, I need some help figuring out all of this documentation.

We need to make sure that we have appropriate supporting documentation for each - the PT survey and the corrective action.

Corrective action: From what I received, the corrective action documentation looks good, as long as the attachments are either labeled or removed from the packet. Now I haven't read the content because I'm trying to see if all pieces are in order.

PT survey:

1. There is no documentation of responses to the questions in the email from me dated 7/3/09 and the email is noted on the front page.
2. The PT survey note from Julie refers to conf. ions. The corrective action documentation and attachments refer to quantification ions and qualification ions. Are these three different types of ions?
3. The note from Julie states that if the data were reporting ignoring the conf. ion criteria that all would pass. This leads to the questions in the email dated 7/3/09. If CDC said to report and ignore the conf. ions, then a chart displaying all of the results and the acceptable ranges for each sample would provide the supporting documentation.

Let me know how you wish to proceed.

Thanks,
Peggy DiNatale